Quality assessment and vascular disease: The analytic imperatives confronting vascular surgeons in the new era

Jonathan P. Gertler, MD, *Boston, Mass.*

Cross-referencing of the word *quality* and Vascular Surgery in medical databases before 1985 results in titles concerned with such aspects of vascular surgery as "quality of the saphenous vein as a determinant of patency in tibial bypass." Little mention of quality related to the classic Donabedian triad of structure, process, and outcomes was made until the 1990s.[1] Nonetheless, Vascular Surgery now seeks the best way to combine the clinical outcomes specific to the field with outcomes measures that assess more difficult metrics such as independence, self-perception of health status, ambulatory ability, and true cost of interventions to patient and society.[2-4] As technologic advances continue at a great pace it is critical for vascular surgeons to lead with regard to quality assessment and implementation of new therapies.

EXISTING EFFORTS IN VASCULAR SURGERY QUALITY ASSESSMENT

The four major themes of quality improvement and quality assessment are methods and measures, information technologies, organizational issues, and the use of quality-related information.[5] Vascular Surgery as an entity has embraced several of these aspects but has not followed through on others. Methods and measures are embodied in the efforts of the Society for Vascular Surgery and International Society for Cardiovascular Surgery, North American Chapter, to regulate reporting standards through ad hoc committees for diagnostic-specific groups, and regional societies have attempted to track individual practices and surgery-specific outcomes through registries, with which there has been admittedly poor compliance. Organizational issues with regard to government agencies are well established in the advocacy by the national societies with regard to the Resource Based Relative Value system and the Health Care Financing Administration's recognition of the value of certain new procedures and diagnostic tests. A quality corollary to these lobbying efforts can be seen in the efforts at granting appropriate accreditation to vascular laboratories, endovascular efforts, and the certificate of vascular qualifications. The penultimate example of organizational efforts at quality control may be yet to come in the establishment of a separate American Board of Vascular Surgery.

We are lacking in the use of information technologies and the application of our analysis of quality issues. Whereas managed care organizations maintain state-of-the-art relational databases and also have a new capability of data warehousing,[6] vascular surgeons primarily follow the model of individual practitioners whose data pools are only accessible when multicenter studies are at play. Without broad-based databases, we are unable to answer many of the questions concerning our outcomes that will prove critical to establishing the efficacy of procedures and the long-term cost-effectiveness of our proposed treatments for vascular diseases.

Lastly, we are lacking in quality measures for vascular interventions. Our efforts have been directed primarily to determining the mortality and morbidity data and technical options of specific procedures or nonoperative therapies of conditions whose natural histories are often undefined. Vascular surgeons have also attempted functional assessment of procedure-specific metrics (e.g., limb salvage in infrainguinal disease)[7] and systemic metrics[8] (e.g., myocardial infarction rates after aneurysm surgery). This is not to belittle the importance of such measures, but rather to serve as a reminder that limb salvage without restored independence or aneurysm repair in an octogenarian that results in a nursing home admission are the very issues, in addition to vascular disease–specific metrics, that we as a society (both Vascular and American), must address.

From the Division of Vascular Surgery, Massachusetts General Hospital, Harvard Medical School.

Reprint requests: Jonathan P. Gertler, MD, ACC 464, Massachusetts General Hospital, 15 Parkman St., Boston, MA 02114.

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There are efforts in this direction. Interest in appropriate screening intervals and size of intervention for aortic aneurysms,[9] the outcome of surgery for the as-yet-undefined categories of symptomatic carotid disease in the 50% to 70% deciles,[10] as well as independent studies on functional (health-assessment based) analyses of vascular surgery procedures[11] are appearing in the surgical literature. Yet the functional studies are few and far between and are taking a back seat to the obviously important natural history studies.

To recognize where the lack of information on quality of life, general health, self perception, and procedure-specific metrics can have a negative impact on our patients and our society of vascular surgeons, it is worth examining several examples. Although infrainguinal bypass grafting for both claudication and limb salvage is probably the most frequently performed vascular procedure, we lack specific information that will be crucial in justifying the performance of these procedures in the years to come. There have been several reports that have indicated that outcomes measures for general health, for example the SF 36 form, can be used with some validity; however, a definitive study has not been conducted.[11]

Numerous examples of large series with excellent short-term results and long-term patency rates can be given to construct a supportive argument for continuing an aggressive stance toward infrainguinal disease. Some larger issues remain unaddressed. It has been demonstrated that unsupervised exercise therapy leads to much poorer outcomes than intervention for occlusive disease in claudication.[12] It also has been suggested that a sedentary lifestyle is a previously unrecognized and major contributing risk factor to coronary events.[13] Does this mean that we are failing our patients by not taking a combined aggressive approach to claudication and risk factor control and that, in fact, our attitude to claudication in certain subgroups is deleteriously unaggressive? An unwillingness to assess the field in a broad-based health context rather than a procedure-specific metric, in fact, may be costing lives or hindering longevity.

Limb salvage, however, is pursued aggressively because of issues ranging from the purported cost to society of amputation and rehabilitation, patient reluctance to accept an amputated limb, and quality measures that suggest that self care, mobility, and vaguely defined "lifestyle" issues all benefit by an aggressive surgical stance. Reports exist, however, that suggest that upwards of 22% of limb salvage patients would be better served by amputation and aggressive rehabilitation.[14] In addition, in some series, despite aggressive revascularization, amputation rates approached 35% at 1 year for patients with critical ischemia.[15] Others suggest that the mortality rate of this patient group (42% at 3 years, with only 25% maintaining the index limb) does not justify the procedure.[16] The truth likely will lie somewhere between these two views. We as a society of vascular surgeons should be leading the charge to define the subsets of patients who will benefit and the subsets who won't, as we enter an era of global caps on health care dollars and assessment of technologies on the basis of quality rendered and cost saved.

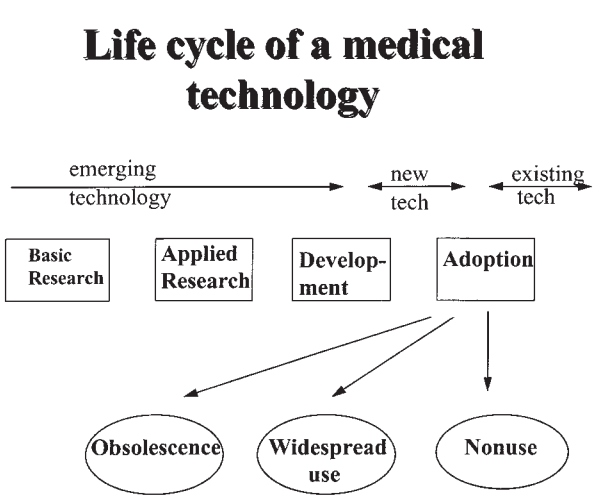

Fig. 1. Life cycle of medical technology.

The flip side of improperly defining the right candidates for aggressive therapies is exemplified by the carotid surgery controversy of the late 1970s and early 1980s. Carotid surgery fell into disfavor because of published reports of high stroke rates achieved by casual carotid surgeons and still-unproved indications for carotid endarterectomy.[17] A decline in the annual frequency of carotid endarterectomy procedures from 170,000 to approximately 85,000 in 1987 can be interpreted as the missed opportunity to prevent 6000 to 8000 strokes that year alone. At costs to society estimated at $30,000 to $150,000, the potential overall cost approached $1 billion per year in 1987. Granted, this is an analysis based on the assumption that all carotid endarterectomy procedures that were not performed would have been performed appropriately. However, the principle that early definition of the validity of a technique can have enormous impact on peoples' health and social costs is still very much at

play. As soon as technology is available to be studied and either validated or not, it should be.

ASSESSMENT OF NEW VASCULAR TECHNOLOGIES

We are at an extremely exciting point in the evolution of Vascular Surgery. Although besieged by issues concerning reimbursement, control of the clinical application of new technologies, and independence as a specialty, we are also on the edge of a revolution in the fashion in which vascular disease is treated. Health care accounted for 20% of venture capital investments in 1997, and the proliferation of devices on the market promises to flood surgeons with choices that we are ill-prepared to make at present.

It is critical for us to focus on clinical outcomes. Fig. 1 demonstrates the life cycle of new technology in our society, referred to in health policy circles as *diffusion*. The stages of technology acceptance are introduction, take-off, maturation, and obsolescence. At the point of maturation and subsequent exponential dissemination, numerous forces are at play. Ease of application, reduction in cost, patient and referring physician demand (often uninformed), and resultant market pressures can generate rapid diffusion of techniques before validity is ensured.

Ease of technical intervention should not lead to what can be termed *indication creep*. With a progressive portion of surgical research funding coming from industry rather than federal government, we must ensure that assessment of new technologies addresses both short-term efficacy and safety (necessary for approval by the Food and Drug Administration) as well as long-term benefit with regard to existing procedures and with regard to unfettered natural histories. It is incumbent on vascular surgeons to demonstrate for all future areas of new technology and potential quality failure that cost is not a driver unless it is tethered to quality. Improved quality with increased initial expenditure can be cost-effective when viewed through the lens of long-term outcomes and should drive an effort to reduce ancillary variable costs associated with the procedure in question so that an advance in quality is not sacrificed to budgetary concerns. Endovascular aneurysm repair, carotid angioplasty, stent-grafts for occlusive disease, minimally invasive venous interventions, and new diagnostic tools should all be included in this type of analysis and scrutiny.

SUMMARY

Vascular Surgery is poised at the edge of a rare moment in medical care. Energy, intelligence, innovation, and resources are available to improve greatly the methods of vascular disease correction. Precedent exists for the overzealous application of technologies. Poor study design and inadequate tracking of outcomes can dilute the value, discredit a critical therapy, and undermine proper patient selection.

The proper analysis of our new technologies will be obtained only through well-organized studies, information systems, and informed organizational oversight. Our analysis must extend beyond procedure-specific outcomes to include quality of life issues measured in a validated and relevant fashion. The present and future of vascular disease therapeutics must reside under the control of those who have devoted their lives to its theory and practice.

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